Meeting Minutes, Open Session, Drug Utilization Review Board October 09, 2019		
Drug Utilization Review Board Meeting Location: DXC Technology, Building #283, Capital Room 6511 SE Forbes Ave, Topeka, KS 66619	**DUR Board Members:** Moneeshindra Mittal, MD (Chair) James Backes, PharmD Jennifer Clair, MD Katie Burenheide Foster, PharmD, MS, BCPS, FCCM LaTonyua Rice, PharmD, CGP Serena Stutzman, APRN Arthur Arthur Snow, MD Roger Unruh, DO **KDHE/DHCF/Contractor Staff:** Annette Grant, RPh. Victor Nguyen, PharmD John Esslinger, M.D. **DXC Technology Staff/KEPRO Staff** Karen Kluczykowski, RPh Kathy Kaesewurm, RN, BSN Ariane Casey, PharmD Harry Vu, PharmD **MCO Staff:** Janette Mueller, RPh, UnitedHealthcare Community Plan Alan Carter, PharmD, Aetna Better Health of Kansas Angie Yoo, PharmD, Sunflower State Health Plan	**Public Attendees**: Phil King; Pfizer, Erin Hohman; Janssen, Krystal Joy; Otsuka, Berend Koops; Merck, Tami Sova; Biogen, Laura Hill, Melissa Basil; AbbVie, Bert Rodriquez; Takeda, Tami Sova; Biogen, Alexander Gresham; Pharmacy Student at University of Kansas. *Illegible names on the sign-in sheet were not included.

TOPIC	DISCUSSION	DECISION
I. Call to Order	Dr. Mittal called the meeting to order at 10:03 a.m. (Quorum met)	
Announcements and Introductions	Ms. Grant reminded the public that at the conclusion of the meeting, we will close off the meeting room, so the DUR Board members can eat lunch. Secondly, Ms. Grant explained the additions to the Board's packet and metrics for the PA program, as well as information related to other state Medicaid programs.	
II. Old Business **A. Review and Approval of July 10, 2019 Meeting Minutes**	**Board Discussion:** The Board Chairman asked for updates or changes needed to the minutes. None requested.	Dr. Foster moved to approve the minutes as stands. Ms. Stutzman seconded the motion. The motion was approved unanimously.
III. New Business **A. New Preferred Drug List (PDL) Class** 1. Acne Agents – Tetracyclines - Oral s	**Background:** At the September 2019 PDL meeting, the committee approved the addition of the Acne Agents-Tetracyclines- Oral to the PDL. The PDL Committee deemed agents are clinically equivalent and this comes to board for final approval. New drugs in this class, including Minolira®, have higher costs. A cost comparison of newer agents to older agents in same class was viewed. **Public Comment:** None. **Board Discussion**: Board member asked if other agents in this class are tried first before going to these more expensive drugs. State answered "Yes".	Dr. Backes moved to approve. Dr. Unruh seconded the motion. The motion was approved unanimously. *note* State reminded the Board that there needs to be 5 affirmative votes to pass.

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2. Hemophilia A Factor VIII Agents - Long Acting - Prophylaxis Use	**Background:** At the September 2019 PDL meeting, the committee approved the addition of the Hemophilia B Factor IX Agents – Long Acting – Prophylaxis Use to the PDL. Four agents being considered for addition to allow state for opportunity for supplemental rebates, since these are expensive drugs. **Public Comment:** None. **Board Discussion:** Board member asked if adding new drugs or indication. State explained that these are not on the PDL currently. Board member asked how many patients we have, state answered that we had ~800 claims last year.	Ms. Stutzman moved to approve. Dr. Claire seconded motion. The motion was approved unanimously.
3. Hemophilia B Factor IX Agents - Long Acting – Prophylaxis Use	**Background:** At the September 2019 PDL meeting, the committee approved the addition of the Hemophilia B Factor IX Agents – Long Acting – Prophylaxis Use to the PDL. Two agents being considered for addition. Addressed Non-Preferred PDL PA Criteria. **Public Comment:** None **Board Discussion:** Board questioned if we needed agents to be broken down into two separate classes. The State responded that it was our process, when multiple agents are available.	Dr. Backes moved to approve. Ms. Stutzman seconded the motion. The motion was approved unanimously.

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B. Revised Prior Authorization (PA) Criteria 1. Adult Rheumatoid Arthritis Agents	**Background:** Prior authorization criteria were initially approved in July 2019. Since that time, Rinvoq® and Hadlima® have become FDA-approved for the treatment of adult rheumatoid arthritis. The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and clinical practice guidelines to provide consistency with similar agents. Removed Truxima® which is a biosimilar for Rituximab but not indicated for RA. Now specifying "immunomodulating biologic" instead of "biologic". Added new JAK inhibitor agent and biosimilars. Updated tables so patients can't get duplicate immunomodulating therapy. Addition of 5 agents total. **Public Comment:** None. **Board Discussion:** Board clarified that if on Xolair® for asthma, cannot get another immunomodulating agent for RA. State explained immunomodulating agents attack immune system putting patient at higher risk for adverse effects and infections. There is an appeals process to make rationales for use, but otherwise agents in this class not allowed to be used concurrently. Will send to external review if many appeals take place, but have not had any so far.	Dr. Backes moved to approve. Ms. Stutzman seconded motion. The motion was approved unanimously.

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2. Atopic Dermatitis Agents	**Background:** These criteria will combine and supersede all previous criteria for agents used for the treatment of atopic dermatitis. The prior authorization criteria are being revised to ensure appropriate use based upon the FDA-approved labeling information and clinical practice guidelines to provide consistency with similar agents. Previously only had Dupixent®. Combining PA criteria and adding three topical agents. Taking old criteria and adding timeframe, previously 8 week trial but now requesting 3 week trial of corticosteroid. If can't use steroid would approve one of these topical agents. Added corticosteroid agents table. **Public Comment:** None. **Board Discussion:** Board asked if for the drug Elidel® still have to be in consultation with a dermatologist. State clarified no, intention isn't to get a referral for use.	Dr. Foster moved to approve as amended. Dr. Backes seconded motion. The motion was approved unanimously, as amended.
3. Crohn's Disease Agents	**Background:** Prior authorization criteria were initially approved in July 2019. The prior authorization criteria are being revised to make a clarification to the initial approval criteria and revisions to renewal criteria. Adding biosimilar to Humira®. Defined remission. Discussed maintaining remission and defined adequate trial of 8 weeks. Treating to target. Removed Crohn's disease activity index. **Public Comment:** None. **Board Discussion:** Board considered criteria is very specific and adding burden to physician offices and MCOs. State explained other states request prerequisite treatment similar to this. The goal of the PA form is to reduce burden on physicians, so this is in line with requirements of other states.	Ms. Stutzman moved to approve. Dr. Foster seconded motion. The motion was approved unanimously.

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	Board member questioned if this process is easier for MCOs to follow for PA. State commented that this is a recent change trying to move to simpler PA process and can be modified if needed and the feedback is that this is easier for everyone involved.	
4. Ulcerative Colitis (UC) Agents	**Background:** PA criteria initially approved in July 2019. Per the Board's request, this PA is being brought back to address the previously discussed step therapy. Previous concerns of requiring treatment with corticosteroids first before moving to biologic agents. Clarifying step therapy and definitions of induction and maintenance of remission in line with the guidelines from the American College of Gastroenterology. **Public Comment:** None **Board Discussion:** Board member clarified induction criteria. Explained that there is different criteria for induction and maintenance to get agents approved. Intent is that if a provider can't meet induce remission and meet the criteria with corticosteroids they wouldn't have to meet maintenance criteria. Board member suggested that PA include "for induction" and "for maintenance" to make it clearer to providers. Adequate trial defined as 4 weeks, conventional maintenance therapy of 4 months from guidelines. Removed C-reactive protein biomarker from PA criteria. Endoscopy is the gold standard and preferred.	Dr. Foster moved to approve. Dr. Rice seconded the motion. The motion was approved unanimously.
5. Multiple Sclerosis (MS) Agents	**Background:** Prior authorization criteria were initially approved in July 2018. Since that time, Mavenclad® has become FDA-approved for the treatment of Multiple Sclerosis. A correction to the table of disease-modifying therapies has been made. The criteria are being updated to the current format and wording for disease-state PA criteria. Added PDL to use first and took out specific safety criteria. Added Mavenclad® and Mayzent® to drug class and added maximum dosing limits.	Dr. Backes moved to approve. Dr. Foster seconded the motion. The motion was approved unanimously.

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	Public Comment: None. **Board Discussion:** The State requested that an addition of "if applicable" be added to the statement to keep consistency in every PA.	
6. Opioid Products Indicated for Pain Management	**Background:** Prior authorization criteria were last revised in April 2019. The prior authorization criteria are being updated to include the short-acting opioids butorphanol and opium. **Public Comment:** None. **Board Discussion:** Board member asked if there are any issues seen with Naloxone since it is being more often prescribed, especially since pharmacists in Kansas can dispense Naloxone. State clarified no issues.	Ms. Stutzman moved to approve. Dr. Claire seconded the motion. Dr. Snow, Ms. Stutzman, Dr. Rice, Dr. Backes, Dr. Foster, Dr. Claire, Dr. Andrew, Dr. Mittal approved. The motion was approved unanimously.
7. Blanket Statement - PDL Criteria Inclusion	**Background:** This revision modifies all prior authorization (PA) criteria to include a statement regarding the current PDL agents. This revision will include the statement "For all agents listed, the preferred PDL drug, where applicable, which treats the PA indication, is required unless the patient meets the Non-Preferred PDL PA criteria." No other changes will be made. **Public Comment:** None. **Board Discussion** State member commented that at the last meeting we added Clinical PA blanket statement to all the Non-Preferred PDL drugs, now adding this statement to the Clinical PA. Sometimes a drug has both a Clinical PA and	Dr. Rice moved to approve. Dr. Foster seconded the motion. The motion was approved unanimously.

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	a PDL PA, want to make it easier for the reviewer to recognize this and streamline the process.	
8. Blanket Statement- List of Immunomodulating Biologic Agents/Janus Kinase Inhibitors	**Background:** This revision updates the tables of immunomodulating biologic agents and Janus kinase inhibitors that are to not be used concurrently. The following prior authorization criteria will be updated: Ankylosing Spondylitis Agents, Asthma Agents, Juvenile Idiopathic Arthritis Agents, Plaque Psoriasis Agents, and Psoriatic Arthritis Agents. No other changes will be made. Showed dates of changes to tables and drugs. **Public Comment:** None. **Board Discussion:** Board member asked to see table that will be added. Table was provided to board members.	Dr. Claire moved to approve. Dr. Foster seconded the motion. The motion was approved unanimously.

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C. Mental Health Medication Advisory Committee (MHMAC) 1. Antidepressant Medications - Safe Use for All Ages	**Background:** Prior authorization criteria were last revised in July 2019. At the August 2019 MHMAC meeting, the committee updated the criteria to include the agents Drizalma Sprinkle®, Symbyax®, and Emsam® as well as revision to the criteria for the agent Spravato®. Spravato® approval process was expedited and that members of the FDA abstained from voting because they didn't believe there was sufficient evidence for approval. It has addiction potential and is expensive, board review of PA criteria needed. **Public Comment:** Erin Hohman, Medical Liason with Jansen, commented on the concerns of the board and agreed with Dr. Mittal that the PHQ-9 is more readily available in the clinical practice setting, and that the HAM-D and MADRS scales are more in the clinical trial setting and what the FDA accepts for the approval. Another concern is the safety, which is why Jansen has a REMS program for Spravato®. The REMS is intended to decrease the risk of serious outcomes associated with sedation and this product, as well as mitigate misuse or abuse. Four key objectives: only administered in medically supervised healthcare settings, patients get 2 hours of monitoring, ensure each patient is informed about adverse events, and enroll patients in a registry to further characterize these risks. Patient population studies included both moderate and severe severity level. The indication for approval was treatment-resistant depression and doesn't classify patients based on disease severity but needs previous treatment failure of at least two antidepressant agents. In the randomized withdrawal study using the new antidepressant with Esketamine vs new antidepressant and placebo, the risk of relapse if patient had achieved remission in the Esketamine group was 50% less than placebo, and 70% less in patients that had improved based upon rating scale. **Board Discussion:** Board member commented that HAM-D and MADRS score not really used and PHQ-9 usually most used rating scale clinically. The State responded that the PHQ-9 is more clinician friendly and validated but that it is a more subjective patient lead score, though not	Dr. Backes moved to approve. Ms. Stutzman seconded the motion. The motion was approved unanimously. *Noted that this needs to be brought back to the next DUR meeting, after review of PHQ9 with the MHMAC members.

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	opposed to using it and would like approval for now and can bring it back for additional discussion at the next meeting. Board member asked if MHMAC is an open or closed meeting and the State responded that MHMAC meetings are open to the public. State commented that the use of PHQ-9 might not be reliable based upon the FDA's comments on it and feels that more rigorous screening tools should be used to differentiate between severe and moderate depression but noted concerns of provider burden and patient outcomes. Board member clarified the section that states "patient must be on an oral antidepressant in conjunction with Esketamine". State replied that the MHMAC requested that it be added to criteria, and that they must be on a new antidepressant upon starting Esketamine. Board asked if approval wasn't obtained today, if they could reevaluate at the next meeting. State responded that this safety criteria would then be left out and the current criteria would be in effect, which would be a concern. That an initial approval now and additional discussion at the next meeting is the suggested option.	
2. Antipsychotic Medications - Safe Use for All Ages	**Background:** Prior authorization criteria were last revised in April 2019. At the August 2019 MHMAC meeting, the committee updated the criteria for the agent Abilify Mycite®, per the DUR Board's request. Other changes were also made to the "Multiple Concurrent Use" section of the criteria. Initially 90 days, but changed to 60 days. The committee previously had an issue with wording of "documented tolerance" with this drug, was changed to "documented benefit and no contraindications to Aripiprazole tablets". **Public Comment:** None. **Board Discussion:** Board noted that there was minimal change to the PA.	Dr. Foster moved to approve. Dr. Claire seconded the motion. The motion was approved unanimously.

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D. Miscellaneous Items 1. Fee-For Service Annual Program Assessment	**Background:** The Annual program assessment for the Medicaid fee-for-service population presented to show drug trends over the past state fiscal year. Average cost per claim trending up due to higher cost agent utilization. Report will be posted to the KDHE Pharmacy website page. **Public Comment:** None. **Board Discussion:** State clarified that this is only fee for service. Board asked if risperidone costs included the long acting injectable and the state responded explaining it included any dosage form. Board member asked what happened in 2013-2014 that caused cost per claim jump. State responded that in 2013 Hep-C drugs were approved and also patients from fee-for-service moved to KanCare.	
2. Prior Authorization (PA) Program Statistics	**Background:** Working with MCO and providers for improvements and changes, standardizing forms and PA criteria which has been received positively. Removed clinical PAs for preferred drugs. Drafted policy changes of 90 day maintenance drug list based upon provider feedback and concern. Working on website and advertising as a resource to providers as well as an email providers can reach out to about issues. **Public Comment:** None. **Board Discussion:** State has reached out to providers for feedbacks about programs and clinics, receiving feedback about changes and recommendations to implement best practices and policies. State commented no way of tracking physician administered drugs and how to track as well as rejected PA claims. State explained this is just the retail side.	

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IV. Open Public Comment	None.	
V. Adjourn	The meeting adjourned at 11:41 a.m.	Ms. Stutzman moved to adjourn. Dr. Backes seconded the motion. The motion to adjourn was approved unanimously.

The next DUR Board meeting is scheduled for January 8, 2019.

All approved PA criteria are posted to the KDHE website- http://www.kdheks.gov/hcf/pharmacy/pa criteria.htm